

## REMARKS

After entry of this Amendment, the pending claims are: claims 1, and 4-21. The Final Office Action, dated August 27, 2010, has been carefully considered. Claims 1, 5 and 6 have been amended to overcome the 35 U.S.C. 112, second paragraph, objections and put the claims in condition for allowance. Support for the amendments to claims 1 and 5-6 and new claim 24 can be found throughout the Specification and Drawings. Accordingly, no new matter has been added. Reconsideration and allowance of the pending claims in view of the above amendments and the following remarks is respectfully requested.

In the Final Office Action, dated October 27, 2010, the Examiner:

- objected to the drawings;
- objected to the Abstract as containing informalities;
- objected to the specification for containing one or more informalities;
- rejected claims 4-6 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention;
- rejected claims 1, and 4-7 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 7,273,496 to Mitchell ("Mitchell") in view of U.S. Patent No. 5,593,447 to Angeli ("Angeli");
- rejected claims 8-13 under 35 U.S.C. 103(a) as being unpatentable over Mitchell in view of Angeli further in view of U.S. Publication No. 2004/0143332 to Krueger et al. ("Krueger");

- rejected claims 14-20 under 35 U.S.C. 103(a) as being unpatentable over Mitchell in view of Angeli and further in view of U.S. Published Patent Application No. 2002/0052656 to Michelson ("Michelson"); and
- rejected claim 21 under 35 U.S.C. 103(a) as being unpatentable over Mitchell in view of Angeli and further in view of U.S. Patent No. 4,759,769 to Hedman et al. ("Hedman").

#### **THE DRAWINGS OBJECTIONS:**

The drawings were objected to because in Figures 1 and 2, according to the Examiner, central axis 2 and swivel axis 3 do not appear to be in the correct positional relationship with respect to swivel axis 4. According to the Examiner, it appears that they should be shifted further back, along swivel axis 4, to be consistent with the disclosure (i.e., page 7, lines 17 and 18) stating that edge 53 forms swivel axis 3. It appears Figure 3 more accurately depicts the correct location of central axis 2. Applicants respectfully submit that Figure 1 does not need any correction as Figure 1 does not show axis 3, or 4 but rather cross sectional Line A-A and cross sectional Line B-B for figures 5 and 6. Applicants have submitted replacement drawing sheet 2 showing revised figure 2 with central axis 2 and swivel axis 3 displaced to be in conformity with the central axis 2 in figure 3. Applicants respectfully submit that no new matter has been added and that such amendment is fully supported by the as-filed specification including, *inter alia*, the Abstract. Withdrawal of this objection is respectfully requested.

#### **THE ABSTRACT OBJECTIONS:**

The abstract was objected to for containing one or more informalities. Applicants respectfully submit that appropriate corrections have been made. Withdrawal of this objection is respectfully requested.

**THE SPECIFICATION OBJECTIONS:**

The specification was objected to for containing one or more informalities. Applicants respectfully submit that appropriate corrections have been made. Withdrawal of this objection is respectfully requested.

**THE 35 U.S.C. 112, SECOND PARAGRAPH, REJECTIONS:**

Claims 4-6 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, claim 4 was rejected because there was insufficient antecedent basis for the term “the first joint section.” Applicants have amended claim 1 to add antecedent basis for the term “the first joint section.” Claim 5 was rejected because the terms “the lower joint section” and the “central joint section” did not have antecedent basis. Claim 5 was amended to overcome this rejection. Claim 6 was rejected because the term “upper joint section” and “the central joint section” did not have antecedent basis. Claim 7 was amended to overcome this rejection. Applicants respectfully submit that appropriate corrections have been made. Withdrawal of these 35 U.S.C. 112, second paragraph, rejections are respectfully requested.

**THE ART REJECTIONS TO INDEPENDENT CLAIM 1:**

Independent claim 1 was rejected as being unpatentable over Mitchell in view of Angeli. Independent claim 1 is directed to an intervertebral implant and recites, as follows:

a central axis, an upper section, suitable for contacting the base plate of a vertebral body lying above, and a lower section suitable for contacting the cover

plate of a vertebral body lying below, wherein: the upper section has a ventral side area, a dorsal side area, two lateral side areas, a top apposition surface, and a bottom surface; the lower section has a ventral side area, a dorsal side area, two lateral side areas, a bottom apposition surface, and a top surface; and the two sections are moveable in relation to each other via two joints arranged between the two sections, wherein: each of the joints has a swivel axis and the two swivel axes are arranged transversely or perpendicular to each other; and **the two joints comprise an upper joint element connected with the upper section, a central joint element, and a lower joint element connected with the lower section**, wherein: each joint comprises a wedge member having a pointed tip for bearing against a second joint section in a way that allows tilting around the swivel axis. (Emphasis added).

The Examiner argues that Mitchell discloses the claimed invention except for each wedge-like member being a wedge member having a pointed tip bearing against the joint section (i.e., pointed depression) in a way that allows tilting around the swivel axis. Angeli, the Examiner argues, teaches a joint (Figure 8B) comprising a wedge member (420 having a pointed tip (44, i.e. www.meriam-webster.com defines a point as the terminal usually sharp or narrowly rounded part or something) bearing against a pointed joint section (43) that allows tilting around a swivel axis defined by the tip (column 2, lines 1-18). The Examiner continues stating that it would have been obvious to a person of ordinary skill in the art at the time of the invention to construct the invention of Mitchell with the wedge member having a pointed tip bearing against a joint section that allows tilting around a swivel axis defined by the tip in view of Mitchell (sic, Angeli) in order to allow for tilting around the swivel axis without generating significant friction.

The Examiner admits that Mitchell in view of Angeli fails to disclose the wedge members being formed on the upper and lower joint elements and the pointed tips being provided on the central joint element. The Examiner then argues that it would be obvious to a person of ordinary skill at the time of

the claimed invention to construct the invention of Mitchell in view of Angeli with the wedge members being formed on the upper and lower joint elements and the pointed tips being provided on the central joint element.

Applicants respectfully submit that there is no disclosure, teaching, or suggestion of combining the three piece intervertebral implant in Mitchell with the two piece femoral implant of Angeli to arrive at an implant having two joints wherein the two joints comprise an upper joint element connected with the upper section, a central joint element, and a lower joint element connected with the lower section, wherein each joint comprises a wedge member having a pointed tip for bearing against a second joint section in a way that allows tilting around the swivel axis.

Mitchell discloses a two piece intervertebral implant comprising a first plate, a second plate and a crossbar there between. The crossbar comprises two round pins or beams each having a length. The crossbar 130 permits the upper plate to rotate or pivot with respect to the lower plate. More specifically, when a patient bends forward or backward the upper plate pivots or rotates about beam 210, and when a patient bends laterally side to side the lower plate pivots or bends about beam 220. Motion in the Mitchell implant is derived from rotation about two axes or lines.

Angeli discloses a two piece femoral implant to replace the standard ball and socket arrangement of prior art femoral implants. The Angeli implant has a shell 11 and a femoral component 18. The shell has an acetabular contact point 13 which represents the apex or vertex of a cone shaped cavity 14 while the femoral component has a femoral vertex 22 for cooperation with the acetabular vertex (contact

point) 13. The femoral vertex 22 is able to pivot about the contact point 13 to provide polyaxial motion around that single contact point.

First, it is respectfully submitted that combining Angeli with Mitchell would not arrive at the invention recited in claim 1. The Examiner argues that it would be obvious to combine the invention of Mitchell with the wedge member having a pointed tip bearing against a joint section **that allows tilting around a swivel axis defined by the tip** in view of Mitchell (sic, Angeli) **in order to allow for tilting around the swivel axis** without generating significant friction. It is respectfully submitted that Angeli does not allow for tilting around a swivel axis as argued by the Examiner but rather provides for tilting about a point or polyaxial motion (as provided by a ball and socket joint), and certainly not tilting about an axis as argued by the Examiner. Combining the joint of Angeli in the implant of Mitchell would not arrive at an implant having two joints, each having a swivel axis and the two swivel axis arranged transversely or perpendicular to each other as claimed, but rather a single joint rotating about a single point. Second, there is no motivation to combine the joint of Angeli in the implant of Mitchell because as explained above, the joints are completely different and provide different types of motion. Angeli provides for a different type of joint than Mitchell as the single joint with the vertex poly-axially rotating on the contact point provides a completely different type of motion than each joint in Mitchell— a motion not provided by or desired in Mitchell given its construction. In addition, it is respectfully submitted that the desired motivation described by the Examiner, to significantly reduce friction, was likely not a problem or recognized concern in the implant of Mitchell.

In addition, it is respectfully submitted that one of ordinary skill in the art, if they were to combine Angeli with Mitchell, would likely replace the three piece implant construction of Mitchell with the two piece implant construction of Angeli to arrive at a one joint construction, rather than a two joint construction arranged between two sections wherein the **two joints each have a swivel axis**. If one attempted to keep the three piece construction of Mitchell (which it is submitted they would not), it is respectfully submitted that incorporating the two piece construction of Angeli for each of the joints in Mitchell would not arrive at the claimed invention (i.e., each joint would not have a swivel axis), but would likely arrive at an unworkable intervertebral implant for the spinal column as it would provide two poly-axial rotation points and likely be too unstable for the spinal column.

For all of these reasons, it is respectfully submitted that the combination of Mitchell in view of Angeli is based upon hindsight reconstruction and rejection of independent claim 1 (and dependent claims 4-21) based upon Mitchell in view of Angeli should be withdrawn.

Furthermore, as claims 4-21 all depend from independent claim 1, it is submitted that these claims are equally allowable. Further claims 5 and 6 expressly state that “the wedge member . . . extends parallel to the swivel axis,” a limitation not met by the joint in Angeli which has a femoral vertex that forms a point and does not “extend parallel” to an axis. Indeed, none of Krueger, Michelson or Hedman remedy the deficiencies of the combination of Mitchell in view of Angeli, and thus claims 8-21 should be allowed. Withdrawal of these rejections and allowance of claims 4-21 is also respectfully requested.

### CONCLUSION

Based upon the above-listed amendments and remarks, Applicants respectfully submit that the present application, including claims 1 and 4-21, is in condition for allowance and such action is respectfully requested.

No fee is believed due for this submission. If, however, the Commissioner determines otherwise, the Commissioner is authorized to charge any fees which may now or hereafter be due in this application to Deposit Account No. 19-4709.

In the event that there are any questions, or should additional information be required, please contact Applicant's attorney at the number listed below.

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Respectfully submitted,  
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